

## **REMARKS**

Claims 1-23 are pending and at issue in the instant case. Claims 7, 12, 17 and 18 have been amended. Claims 24-27 have been cancelled. Claims 28-31 are withdrawn.

Claims 1, 11-12, 14 and 17 were rejected under 35 USC 112, second paragraph because, according to the Office Action, the term “separation modifier” is unclear. According to the Office Action, it is unclear whether a separation modifier means any moiety that confers a separation characteristic upon a probe or any means of electrophoretic separation. Separation modifier is clearly set forth in the specification (*see*, for example, MPEP 2172 et seq) as a moiety that confers upon the probe or reporter molecule containing it a separation characteristic that allows separation of each probe or reporter molecule from all other probes and molecules of a designated set (*see* page 12, lines 9-14). The term particularly points out and distinctly claims the metes and bounds of the invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 7 was rejected under 35 USC 112, second paragraph because, according to the Office Action, the claim recitation “...wherein said incubating is carried out in a single well containing a plurality of different cells, each containing a different probe...” is unclear because either different types of cells or similar cells with different probes may be contemplated. This rejection is respectfully traversed because the word ‘different’ as it modifies the word ‘cells’ is intended to mean that the cells are different, one from another without probes, as well as different because of probes; that meaning is within the scope of the word and support for both meanings can be found throughout the disclosure (*see*, for example, page 36, line 14 et seq and page 38, line 1 et seq) and the word particularly points out and distinctly claims that which is the subject matter of the claim (*see*, for example, MPEP 2173 et seq). Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claim 7 was also rejected because, according to the Office Action, it was unclear whether the tags were released from their binding moieties within the cell or whether the tags were released into the extracellular matrix or both. Claim 7 has been amended to recite that released tags are obtained from the well, and the amended claim particularly points out and

distinctly claims the subject matter. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

Claim 12 was rejected under 35 USC 112, second paragraph, because, according to the Office Action, T<sub>3</sub> does not appear in the pictured structure of the probe and because it was unclear whether “S” is the designation given to the substrate or to the enzyme. Claim 12 has been amended to delete T<sub>3</sub> and to make it clear that the designation “S” applies to the substrate. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claim 17 was rejected under 35 USC 112, second paragraph, for lack of antecedent basis. The claim has been amended to recite “a” in place of “the.” Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claim 18 was rejected under 35 USC 112, second paragraph because, according to the Office Action, it was not clear which cell was being referenced. The claim has been amended to recite the “cells” recited throughout claim 1. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-23 were rejected under 35 USC, 112, first paragraph, for failing to comply with the written description requirement. According to the Office Action, the claims were rejected because they do not provide structural information with regard to the enzyme sequences capable of cleaving probes. The rejection under this rationale is traversed for the following reasons.

The written description requirement is satisfied when the description clearly allows persons skilled in the art to recognize what has been invented (*see*, In Re Gosteli, 872 F.2d 1008, 1012, 10 USPQ 2d 1614, 1618 (Fed Cir. 1989); MPEP 2163 et. Seq.). Claim 1 recites a “...promoter operatively linked to the coding sequence for an enzyme having selected enzymatic activity...” Structural information, for example sequence information of an enzyme having selected enzymatic activity, would be readily available to one skilled in the art once a desired enzyme has been selected. Structural information would not be required for one skilled in the art to recognize what has been invented, and the claim satisfies the

written description requirement in that sense. Accordingly, reconsideration and withdrawal of the rejection according to that rationale are respectfully requested.

The Office Action also rejects the claims under the written description requirement because "...no mention is made of which separation modifiers could be attached to which probes..." The rejection under this rationale is traversed for the following reasons.

Written description is satisfied through sufficient description of a representative number of species, that number which is adequately described so as to represent the entire species (*see* MPEP 2163 et seq.) The claims need not describe every single feature, and what is well known to one of ordinary skill in the art may be preferably omitted from the disclosure (*see* *Hybritech Inc. v. Monoclonal Antibodies Inc.* 802 F.2d. 1384, 231 USPQ 94). According to the Office Action, no mention is made of which separation modifiers may be attached to which probes. What is conventional or well known to one of skill in the art need not be disclosed and is preferably omitted (*see* *Hybritech Inc. v. Monoclonal Antibodies, Inc.* 802 F.2d 1384). The techniques of molecular biology are well know, and Applicants need not teach which separation modifiers may be attached to which probes. Accordingly, the written description requirement of the instant invention is satisfied without teaching basic techniques of molecular biology. Reconsideration and withdrawal of this rejection under this specific rationale are respectfully requested.

The Office Action rejects the claims under the written description requirement because the results are not necessarily predictive of any other enzyme capable of cleaving the probes. The rejection under this rationale is traversed for the following reasons.

An applicant will be entitled to an entire genus when the species disclosed are sufficient to enable one skilled in the art to predict the entire genus from that disclosed (*see* MPEP 2163 et seq). Claim 1 recites enzymes capable of cleaving probes into a substrate moiety and an electrophoretic tag (an e-tag, as disclosed, for example, in United States Serial Number 09/698,846, now United States Patent 6,627,400, incorporated by reference on page 23, line 12). Given the disclosure, (as well as the cited patent) one skilled in the art would know which enzymes are capable of cleaving probes into a substrate moiety and an e-tag. Thus, the claims satisfy the written description requirement in that sense. Accordingly,

reconsideration and withdrawal of this rejection under this specific rationale are respectfully requested.

Claims 1-23 were rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and use the invention. According to the Office Action, it is clear that one skilled in the art would have to conduct a large number of experiments to determine which enzymes could be used with which probes, and the unpredictability is exacerbated by the large genus of enzymes and probes used. This rejection is traversed.

The test of enablement is not whether any experimentation is required, or even whether a great deal of experimentation is required, but whether the disclosure and the art at the filing date of the application are sufficient to allow one skilled in the art to practice the claimed invention without undue experimentation. The invention is drawn to a multiplexed assay, as set forth in claim 1. One skilled in the art would be able to select an enzyme to practice the assay, in spite of the large genus of enzymes (*see*, for example, United States Serial Number 09/698,846, now United States Patent 6,627,400, which was incorporated by reference, for example, on page 23, line 12, of the instant specification). One skilled in the art would be able to make and/or use the claimed invention without undue experimentation using the disclosure, as filed, as well as the prior art at the filing date of the application. Accordingly, the claims are enabled. Reconsideration and withdrawal of the rejections are respectfully requested.

## CONCLUSION

Applicants believe that the claims of the instant application meet all of the conditions for patentability and are in condition for allowance. Accordingly, an early indication of the same is respectfully requested.

No fees are believed to be due with this response. However, pursuant to 37 C.F.R. §1.136 (a)(3), the Commissioner is authorized to charge all required fees, or credit any overpayment, to Account Number 19-2555. By his signature affixed to Page 15 of this submission, Applicants' representative hereby represents that he is authorized to represent the Applicants pursuant to Rule 34(a) of the Rules of Practice.

Respectfully submitted,  
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Dated: November 7, 2006

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